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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTELLAS PHARMA INC.; ASTELLAS US LLC; and ASTELLAS PHARMA US, INC., Plaintiffs, v. SANDOZ INC., Defendant.	C.A. No. 2:23-cv-01214 (ES) (JSA)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to L. Pat. R. 4.3 and the Court's Pretrial Scheduling Order (Dkt. No. 43), Plaintiffs Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc. (collectively, "Astellas" or "Plaintiffs") and Defendant Sandoz Inc. ("Sandoz") hereby submit this Joint Claim Construction and Prehearing Statement regarding U.S. Patent No. 10,786,500 (the "'500 patent") (the "Asserted Patent" or "Patent-in-Suit").

I. CONSTRUCTION OF THOSE TERMS ON WHICH THE PARTIES AGREE

Pursuant to Local Patent Rule 4.3(a), the parties identify the following term for which the parties have reached an agreed-upon construction:

Claim Term	Agreed-Upon Construction
"6-ethyl-3-({3-methoxy-4-[4-(4-methylpiperazin-1-yl) piperidin-1-yl]phenyl}amino)-5-(tetrahydro-2H-pyran-4-ylamino)pyrazine-2-carboxamide hemifumarate" (claims 1-11)	"gilteritinib hemifumarate"

II. PROPOSED CONSTRUCTION OF DISPUTED TERMS

Pursuant to Local Patent Rule 4.3(b), attached hereto as Exhibit A is a claim chart identifying the claim term in dispute, the parties' proposed constructions, and the evidence (both intrinsic and extrinsic) that each party intends to rely on in support of its proposed construction or to oppose the other party's proposed construction. The disputed claim term and the asserted independent claims in which it appears are set forth below:

Claim Term(s)
"pharmaceutical additive" (claims 1-11)

III. IDENTIFICATION OF MOST SIGNIFICANT TERMS

Pursuant to Local Patent Rule 4.3(c), the parties identify the following term as most significant to the resolution of the case: "pharmaceutical additive."

IV. ANTICIPATED LENGTH OF CLAIM CONSTRUCTION HEARING

Pursuant to Local Patent Rule 4.3(d), the parties anticipate that the Claim Construction Hearing will require 1 hour. The parties do not anticipate a need to provide a technology tutorial at the Claim Construction Hearing at this time.

V. IDENTIFICATION OF WITNESSES

Pursuant to Local Patent Rule 4.3(e), the parties do not presently intend to call any witnesses at the Claim Construction Hearing. The parties intend to promptly inform the Court if that understanding changes.

Dated: December 18, 2023

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EXHIBIT A: DISPUTED TERMS AND EVIDENCE FOR U.S. PATENT NO. 10,768,500

Claim Term	Astellas's Proposal & Evidence	Sandoz's Proposal & Evidence
"pharmaceutical additive" (claims 1-11)	Plain and ordinary meaning, which is an ingredient other than the active pharmaceutical ingredient **Intrinsic Evidence:** '500 Patent and its file history generally, including but not limited to the '500 Patent at Abstract, 1:15- 22, 1:51-4:51, 5:62-66, 6:41-8:55, 9:6-45, 9:55- 10:6, 10:17-37, 10:59-17:55 (including all Examples & Tables), claims 1-11 and the '500 Patent's file history generally, including but not limited to, Preliminary Amendment & Applicant Remarks (Jan. 2, 2018), Requirement for Restriction (June 28, 2018), Response to Restriction & Applicant Remarks (July 23, 2018), Non-Final Rejection (Sept. 20, 2018), Amendment After Non-Final Rejection & Applicant Remarks (Mar. 19, 2019), Final Rejection (June 26, 2019), Amendment & Applicant Remarks (Dec. 16, 2019), Applicant Initiated Interview Summary (May 28, 2020), Notice of Allowance (July 7, 2020), Notice of Allowance (Aug. 18, 2020), Applicant Summary of Interview (Aug, 18, 2020). **Extrinsic Evidence:** SANDOZ-GILT00036111-480.	"an additive that is capable of controlling water content in a pharmaceutical formulation during a formulation step and/or storage" **Intrinsic Evidence:** '500 Patent generally, including but not limited to, Claims 1-11, Abstract, 1:15-22, 1:51-4:17, 5:62-66, 6:41-8:55, 9:6-45, 9:55-10:6, 10:17-37, 10:59-11:20, Examples (11:21-17:47, including Tables 1-6); 17:49-55. '500 Patent file history generally, including but not limited to, Preliminary Amendment & Applicant Remarks (Jan. 2, 2018), Requirement for Restriction (June 28, 2018), Response to Restriction & Applicant Remarks (July 23, 2018), Non-Final Rejection (Sept. 20, 2018), Amendment After Non-Final Rejection & Applicant Remarks (Mar. 19, 2019), Final Rejection (June 26, 2019), Amendment & Applicant Remarks (Dec. 16, 2019), Applicant Initiated Interview Summary (May 28, 2020), Notice of Allowance (July 7, 2020), Notice of Allowance (Aug. 18, 2020), Applicant Summary of Interview (Aug, 18, 2020). **Extrinsic Evidence:** SANDOZ-GILT00036111-480: Communication Dated Aug. 9, 2019 from Gille Hrabal in file history for European Application No. 16821324, pp. 1-6 (SANDOZ-GILT00036270-75).

EXHIBIT A: INITIAL CLAIM CHART FOR U.S. PATENT NO. 8,283,380

	Additional Evidence: Plaintiffs may rely on expert testimony establishing: (1) that a POSITA would understand the claims to have Plaintiffs' preliminary proposed construction; and/or (2) that a POSITA would understand the claims, specification, and file history to support the Plaintiffs' preliminary proposed construction. Plaintiffs may also rely on expert testimony to oppose Defendant's proposed construction and/or to rebut any evidence or expert testimony provided by Defendant related to the construction of this term, including but not limited to any testimony or opinions that a POSITA would have understood the term "pharmaceutical additive" to have the meaning proposed by Sandoz, a POSITA's understanding of the claims, specification, file history and other identified evidence, and a description of the relevant technology and the knowledge of a POSITA.	**Additional Evidence:** One or more experts may provide affirmative and/or rebuttal testimony, including (1) that a POSA would have understood the term "pharmaceutical additive" to have the meaning proposed by Sandoz, (2) that a POSA would have understood the claims, specification, and file history to support the meaning proposed by Sandoz, (3) that a POSA would not have understood the term "pharmaceutical additive" to have Plaintiffs' proposed construction, (4) that a POSA would not have understood the claims, specification, and file history to support Plaintiffs' proposed construction, (5) a POSA's general understanding of the claims, specification, and file history and other identified evidence, and/or (6) a description of the relevant technology and the knowledge of a POSA. Such testimony may be provided by one or more experts qualified in the field of pharmaceutical formulation.